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THE DEVELOPMENT SERVICES COMPANY

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December 15, 1999

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 10-61
Rockville, MD 20852

Re: [Docket No. 99D-4396]
Draft Guidance for Industry on Financial Disclosure by Clinical Investigators

Dear Sir or Madame.

Reference is made to the Federal Register Notice of October 26, 1999 (Volume 64, Number 206), Docket No. 99D-4396, Draft Guidance for Industry on Financial Disclosure by Clinical Investigators. The reference notice solicited comments on the referenced draft guidance. Below, we are providing comments on said guidance:

Question 5, "What does FDA mean by the definition "sponsor"?" The answer given is " FDA means the party or parties who provide material support for a particular study at the time it is carried out (e.g. who provides funding and/or test articles needed to initiate the study)." The answer should be expanded to differentiate between a sponsor and a Contract Research Organization (CRO) that has assumed some of the responsibilities of the sponsor. For example, a CRO may assume responsibility for selection of investigators and be responsible for payments to investigators. Unless said payments are derived from assets of the CRO, with the CRO having an ownership position in the investigational product, the CRO would not be considered a sponsor. As long as a person or organization acts independently, and is merely distributing funding provided by the sponsor, the CRO would not be considered a sponsor-CRO. It is important that the final guidance address the difference between a CRO and a sponsor-CRO. This issue is also pertinent to the answer to question 7, "Is it necessary to collect financial information from investigators who have financial interests in CROs?" The definition of sponsor stated as "(providing material support for the study)" should be revised to reflect the comments above.

Under question 6, "If a Contract Research Organization (CRO) is conducting a covered clinical study, should the CRO or the sponsor collect the financial information from investigators? Should the CRO or the applicant sign the certification/disclosure forms?" The answer given states "Whether or not the

99D-4396

C2

CRO collects the financial information from investigators and signs the forms depends upon the contractual responsibilities that have been transferred to the CRO." We agree that collection of financial disclosure is dependent on the transfer of responsibilities to the CRO; however, signing the disclosure certificate can only be the responsibility of the sponsor. Therefore, we believe that this answer should be amended to read: "Under 21 CFR 54.4, clinical investigators subject to the IND or IDE regulations must provide sponsors with information needed to allow subsequent disclosure or certification. Whether or not the CRO collects the financial information from investigators depends upon the contractual responsibilities that have been transferred to the CRO.. . . . The sponsor should sign the certification and/or disclosure forms." Our position stated above is consistent with the Summary of Comments in the final rule, Financial Disclosure by Clinical Investigators, published on February 2, 1998. The summary statement referenced is "FDA believes that the collection of information required by this regulation and the preparation and submission of a certification statement would not be onerous. Firms who contracted for covered studies would already have on hand all information pertaining to financial arrangements with clinical investigators and significant payments of other sorts; proprietary interests (e.g. patents) of clinical investigators; and equity interests of investigators in nonpublicly traded enterprises. Applicants who were the sponsors of covered studies would need only to obtain from investigators information on the clinical investigator's equity interests in the applicant, a step that would be necessary only if the applicant is publicly traded. Applicants who did not contract for covered studies must obtain the required information from the sponsor of the covered studies and the investigators or demonstrate conclusively that it was not possible to do so." The Summary Comments correctly identify that the sponsor would have access to information that would allow them to make the required disclosure. A nonsponsor CRO would not have access to such information and therefore would not be in a position to make the required certification.

Question 12, "The rule requires that investigators are required to provide information on financial interests during the course of the study and for one year after completion of the study (see 54.4 (b))? What does "completion of study" mean?' The draft guidance does not clarify the requirements for investigators that are participating in studies involving multiple investigators. In the case of studies involving multiple investigators, is the investigator's responsibility to provide updates for one year after they have provided their last data update for the study or is it one year from the time the last investigator participating in the study provides the last data input?

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Should you have questions or comments or would like to discuss the comments provided, free to call me at (609) 452-4356.

Sincerely,

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